Attachment 5
510(K) Summary
Cortex CO2 / Er:YAG Laser System

K110897

JUL - 1 2011

This 510(K) Summary of safety and effectiveness for the Cortex CO2 / Er:YAG Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Sandstone Medical Technologies, LLC
Address:	105 Citation Court Birmingham, AL 35209
Contact Person:	Mark Rohrer
Telephone: Email:	205-290-8251 – phone ssmed@bellsouth.net
Preparation Date:	March 19, 2011
Device Trade Name:	Cortex CO2 / Er:YAG Laser System
Common Name:	CO2 Laser Er:YAG Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	LS-40 CO2 Laser System (K)093793 MLT Erbium:YAG Laser System (K)032599
Description of the Cortex CO2/Er:YAG Laser System:	The Cortex system and controls are contained in a single console. Electrical power is supplied to the console by the facility's power source. The CO2 laser is delivered via an articulated arm that is permanently attached to the console. There is an additional Er:YAG handpiece that attaches to a port on the console and contains the laser cavity in the head of the handpiece. The user interface is a touch screen located on the console.The user activates the laser emission by means of a footswitch.
Intended use of the Cortex CO2 / Er:YAG Laser System	The CO2 laser is indicated for coagulation, vaporization, ablation or cutting of soft tissue in dermatology and plastic surgery, general surgery, podiatry and otorhinolaryngology. The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

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Performance Data: None

Results of Clinical Study: None

Summary of Technological Characteristics:

Technical Specifications Comparison for the CO2 Laser (including console specification)

	Sandstone Medical Technologies LLC Cortex CO2 / Er:YAG Laser System	Sandstone Medical Technologies LLC CO2 Laser (Predicate Device)
Laser type	Sealed-off CO2 laser tube	Sealed-off CO2 laser tube
Wavelength	10.6 micron (10,600nm)	10.6 micron (10,600nm)
Power to tissue	0.5 -40 W	0.5 -40 W
Super pulse peak power	500W	500W
Laser operation modes	CW, Super pulse	CW, Super pulse
Tissue exposure modes	Continuous, Single Pulse, Repeat Pulse	Continuous, Single Pulse, Repeat Pulse
Aiming beam	3mW (650nm diode) adjustable	3mW (650nm diode) adjustable
Articulated arm	7-joint articulated arm	7-joint articulated arm
Working radius	130cm	130cm
Cooling type	Closed loop liquid	Closed loop liquid
Power input requirements	110VAC/60Hz or 220VAC/50Hz +/- 10%	110VAC/60Hz or 220VAC/50Hz +/- 10%
Dimension (Wide)	34cm	34cm
(Depth)	46cm	46cm
(Height)	96cm	96cm

Technical Specifications Comparison for the ER:YAG Laser Handpiece

	Sandstone Medical Technologies LLC Cortex CO2 / Er:YAG Laser System	Sandstone Medical Technologies LLC Er:YAG Laser (Predicate)
Wavelength	2940nm	2940nm
Max Power	2.4 W	2.4 W
Max Fluence	8 J/cm2	8 J/cm2
Pulse Width	300 µs	300 µs
Repetition Rate	Up to 10 pulse per second	Up to 10 pulse per second
Spot Size	1.5mm, 3mm, 6mm, 9mm	1.5mm, 3mm, 6mm, 9mm

Conclusion:	The Cortex CO2 / Er:YAG Laser System is comparable to the predicate device in terms of indications for use, technical specifications, operating performance features, general design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sandstone Medical Technologies, LLC
% Mr. Mark Rohrer
Managing Member
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Homewood, Alabama 35209

JUL - 1 2011

Re: K110897
Trade/Device Name: Cortex Co2/Er:YAG Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and in plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 18, 2011
Received: May 24, 2011

Dear Mr. Rohrer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110897 K Pending

Device Name: Cortex Co2 / Er:YAG Laser System

The CO2 laser is indicated for coagulation, vaporization, ablation or cutting of soft tissue in dermatology and plastic surgery, general surgery, podiatry and otorhinolaryngology.

The Er:YAG handpiece is designed specifically for superficial skin ablation resulting in skin dermabrasion, and the treatment of wrinkles. In addition this system is intended for coagulation, vaporization, ablation, or cutting of soft tissue (skin) in dermatology, plastic surgery (including aesthetic surgery).

Prescription Use ___xx___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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